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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,769	05/31/2001	Dennis M. Brown	A-70600/RFT/AMS	1226

7590

07/16/2002

FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP
4 Embarcadero Center - Suite 3400
San Francisco, CA 94111-4187

EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/16/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,769

Applicant(s)

BROWN, DENNIS M.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-10, and 14 are pending in the instant application. Claims 11-13 are cancelled.

Response to Amendment

1. The amendment filed 5/6/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New Claim 14, drawn to a solid tumor.

Applicant is required to cancel the new matter in the reply to this Office Action (see pages 6-8).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 4-10 are rejected under 35 U.S.C. 103 as being obvious over Barnett et al. (U.S. Pat. No. 6,103,487).

Barnett teaches the treatment of cancer, and the regression of cancerous tumors (col. 8, lines 27-30). Aqueous solutions can be made with the invention, such solutions containing excipients from hexitol anhydrides (col. 9, lines 65-66). The suspensions can

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further contain antineoplastic agents such as doxorubicin, daunorubicin, and cisplatin (col. 13, lines 16 and 24).

Barnett does not teach that hexitol is used in an amount to modulate the disease, however excipients are known to be used in various amounts. In this case, hexitol is used as a dispersing agent, which is normally used in amounts that fall within the range disclosed on page 6 of the specification.

It would have been obvious to one with ordinary skill in the art to use a well-known excipient such as hexitol, and modify the amount used to optimize the invention. Thus, the instant invention is obvious.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis (U.S. Pat. No. 4,797,388), further in view of Levin et al. ("Chemotherapeutic approaches to brain tumors.").

Francis relates to improved pharmaceutical compositions containing galactitol as a carrier for a therapeutic agent. The agent may be cisplatin, or any substance which is anti-tumor. The galactitol is taught to enhance the chemical and physical stability of the drug.

Levin teaches that the antitumor activity of hexitol may be enhanced by drug combination therapies. Through BCNU-dianhydrogalactitol combination studies, it is suggested that, under the right conditions, hexitol epoxides may be enhanced by drug combination therapies.

Motivation to utilize dianhydrogalactitol in combination with an anti-tumor drug such as cisplatin would have arisen because one of ordinary skill would know that the dianhydrogalactitol would enhance the chemical and physical stability of the cisplatin, and the dianhydrogalactitol may have been enhanced by through the drug combination.

Response to Arguments

4. Applicant's arguments filed 5/6/02 have been fully considered but they are not persuasive.

Regarding the rejection made under 35 U.S.C. 102(e), Applicant asserts that Barnett does not teach that excipients can modulate a proliferative disease. In the instant application, modulation is defined as the reduction in tumor growth (page 3, lines 23-25). Barnett clearly teaches the regression of cancerous tumors. Thus, it is the examiner's position that Barnett teaches the modulation of proliferative diseases and the amounts of excipients to modulate the diseases. Nonetheless, the rejection has been deleted in favor of a rejection under 35 U.S.C. 103(a) over Barnett.

Applicant next relies on the argument that Barnett does not teach the disease modulation is greater than modulation by the antiproliferative agent alone. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is noted that the features upon which applicant relies (i.e., disease modulation greater than modulation by the antiproliferative agent alone) are not recited in the rejected claim(s).

Regarding the rejection under 35 U.S.C. 103(a), applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Whereas Francis does not teach a DAG, Levin clearly teaches the use of such in combination. Whereas Levin does not teach a cisplatin, Francis clearly teaches the use of one in combination with galactitol.

As stated above, Applicant cannot rely upon features not recited in the rejected claims, namely disease modulation greater than modulation by the antiproliferative agent alone.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, motivation to utilize dianhydrogalactitol in combination with an anti-tumor drug such as cisplatin would have arisen because one of ordinary skill would know that the dianhydrogalactitol would enhance the chemical and physical stability of the cisplatin, and the dianhydrogalactitol may have been enhanced by through the drug combination.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

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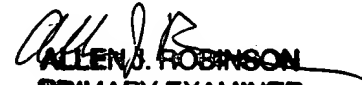
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-

1235.

RMD

July 12, 2002


ALLEN J. ROBINSON
PRIMARY EXAMINER